FDA "Permanent Injunction" Barring C. R. Canfield Co, Inc. Products (10/06) UPDATE (1/07) Click Here for information on alternatives to Canfield's D.S. Dressing for Dry Socket Treatment.

DECS recently became aware that the Food and Drug Administration (FDA) is advising dental professionals and consumers to stop using and discard any product from C. R. Canfield Co., Inc. (http://www.fda.gov/bbs/topics/NEWS/2006/NEW01481.html). The FDA recently obtained evidence that C. R. Canfield Co. manufactured and distributed unapproved drugs and drugs that do not satisfy current good manufacturing practice. C. R. Canfield Co., Inc. produces four products intended for the treatment of alveolar osteitis (i.e., dry socket syndrome):

- D. S. Mini-Dressing (20% Eugenol),
- D. S. Dressing (20% Eugenol),
- D. S. Syringe (20% Eugenol), and
- D. S. Ointment (20% Eugenol).

Dental clinic commanders and individual licensed providers should review the attached USAF HQ USAF/SGOD Policy Letter (P06-06) and the information on the FDA Web site.

Click Here for the USAF HQ USAF/SGOD Policy Letter (P06-06) (DotMil).

Click <u>Here</u> for FDA information.

Alternatives to Canfield's D.S. Dressing for Dry Socket Treatment (1/07)

Question: With the Air Force policy banning the use of C. R. Canfield's D.S. Dressing for dry socket treatments, what should be used as an alternative?

Answer: The Air Force Dental Service published Policy Letter P06-06 in October 2006 following an FDA injunction against C.R. Canfield Co. that barred the use of D.S. Dressings in Air Force health-care facilities. Canfield dressing contained 20% eugenol as an active ingredient and was packaged for individual use. The company has stated that it intends to retool its manufacturing process, comply with government regulations, and be back on the market in the near future.



Unfortunately, until this product is available again DECS has not found a similar product that is packaged for individual use. The Air Force Consultant for Oral and Maxillofacial Surgery has issued a <u>Point Paper</u> on alternative dressing materials for the treatment of localized alveolar osteitis (i.e., dry socket).

Resorbable and non-resorbable materials are both listed as suggestions for dry socket treatment. Alvogyl, a resorbable, radiopaque material contains eugenol and butamben as active ingredients. The product is placed directly into the extraction site. It can be purchased from Septodont [(800) 872-8305, www.septodont.com] or from dental distributors (e.g., Henry Schein). The retail price is \$58.99 per jar from Septodont and each jar can treat approximately 60 sites. Sultan Dental Products [(800) 238-6739, www.sultanhealthcare.com] markets Sultan Dry Socket Paste that can be applied to a nonresorbable gauze strip. Active ingredients include eugenol and 1.6% chlorobutanol. The Sultan paste is sold in a one ounce jar from distributors for approximately \$70.00 or in a case of 12 jars for \$540.00 from Sultan.



Another nonresorbable product is Dressol-X from Rainbow™ Specialty and Health Products, Inc [(800) 268-3384, www.rainbowspecialty.com]. This medicament is premixed and has a radiopaque marker; however, it contains aspirin and cannot be used on patients with ASA allergy or G6PD deficiency.

When a gauze strip is used to place a medicament into an extraction site, DECS recommends that the strip have a radiopaque marker. Ace Surgical Supply [(800) 441-3100, www.acesurgical.com] makes a ¼" gauze strip with a radiopaque filament sewn into it. This gauze strip can also be used with locally mixed Tappe paste or eugenol liquid with or without an emollient (petroleum jelly) as an alternative to a commercially-produced product. When a nonresorbable gauze strip is used in treatment of dry socket, only one strip should be placed into any single extraction site. Removal of the nonresorbable dressing must be confirmed by the provider.

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Reference

Smith D. Alternative Dressing Materials for the Treatment of Localized Alveolar Osteitis. Point Paper. December 2006.